

K822125 MODEL 57000 NASO-CONJUNCTIVA ISOL. MASKAug 27, 1982
39 days to decision

K822125 · Ophthalmic

Source: <https://www.510kdatabase.net/k822125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Jul 19, 1982
Decision date	Aug 27, 1982
Days to decision	39 days
Third-party review	No

APPLICANT

Company	Welch Allyn, Inc.
Location	Mchenry, IL, US
Website	http://www.welchallyn.com/
510(k) history	111 submissions · 111 cleared · 1977-2025

Welch Allyn, Inc. is a medical device manufacturer based in McHenry, US. The company specializes in patient monitoring and diagnostic equipment for healthcare settings. Welch Allyn has maintained a strong FDA 510(k) regulatory record since 1977. The company has received FDA 510(k) clearances from total submissions. Cardiovascular monitoring devices represent the dominant category in recent clearances, including the Connex vital signs monitor series and central station systems. The company's latest clearance in 2025 demonstrates continued regulatory activity and product in...